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EXAMINER

SINGH, SATYENDRA K

ART UNIT	PAPER NUMBER
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1657

NOTIFICATION DATE	DELIVERY MODE
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09/30/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/578,324	Applicant(s) KOLARI ET AL.	
	Examiner SATYENDRA K. SINGH	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 0609.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 May 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/4/06; 9/5/06; 2/9/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response (and claim amendments) filed on 07/06/2009 is duly acknowledged.

Claim 14 (group III) has been canceled by applicants.

Claims 1-13 (groups I and II) are currently pending in this application.

Election/Restrictions

Applicant's election with **traverse of group I** (claims 1-10; directed to **a method for detecting the presence of biofilm-forming microorganisms**, as specifically recited in claim 1) in the reply filed on 07/06/2009 is duly acknowledged. The traversal is on the ground(s) that “...*the prior art cited by the Examiner fails to disclose steps (c)¹ and (d)² of Applicants' process...*”(see remarks, page 6, 3rd paragraph, in particular). This is not found to be persuasive because the steps of the method cannot constitute a special technical feature of the instant invention as the method of group I uses the assembly kit of the second group (i.e. the invention of group II). A special technical feature is an element that is in common in all the groups that defines a contribution over the art. In the instant case, the “sampler device” having “plurality of elongated protusions connected to a support” for enabling microorganisms to form a biofilm (see claim 11, in particular), constitutes the special technical feature of the invention as claimed, and since, such sampler device (for use in the same method) has been fully disclosed and/or made obvious in the cited prior art (see rejection below over Schapira et al, taken with Ceri et al, US 2001/0049975 A1; IDS), the inventions of groups I and II as currently recited lack unity.

The requirement as set forth in the previous office action by the examiner is still deemed proper and is therefore made FINAL.

Claims 11-13 (non-elected invention of group II) are withdrawn from further consideration.

Claims 1-10 (elected invention of group I) are examined on their merits in this office action.

Drawings

The informal drawing (submitted by applicants on 05/04/2006) is not of sufficient quality to permit examination. Accordingly, replacement drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to this Office action. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. Failure to timely submit replacement drawing sheets will result in ABANDONMENT of the application.

Claim Objections

1. Claim 7 is objected to because of the following informalities: claim recites the limitation of "**whereby, when brought in the process**", which should be amended to recite "whereby, when brought **into** the process" in order for the claim recitation to be clear and unambiguous. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the preamble "*a method for detecting the presence of biofilm-forming microorganisms in a paper or board making process* for determining the need of an anti-biofilm agent in the process", which indicates that the idea is to detect microorganisms IF THEY ARE PRESENT. It is unclear as to why the method steps as recited (see step (a) through (d) in claim 1, in particular) assume that the microorganisms that form biofilm are necessarily present in "the process line". Thus, it is unclear whether the method as claimed is a "method for detection" of biofilm-forming microorganisms, or a "method for screening" anti-biofilm agents. Appropriate explanation/correction is required. Since, claims 2-10, directly or indirectly depend from the broader claim 1, they are also rejected under 35 U.S.C. 112, second paragraph as being indefinite.

Claims are being interpreted as being directed to "a method for detecting the presence of biofilm-forming microorganisms..." for the purpose of this office action.

2. Regarding claim 3, the phrase "**e.g.**" or "**preferably**" (taken as "for example") render the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

In addition, regarding claim 3, the phrase "**such as**" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Also, claim 3 recites the limitation "**the optional treatment step**" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

3. Claim 8 recites the limitation "**the protrusions**" in line 5 of the claim. There is insufficient antecedent basis for this limitation in the claim. Perhaps this claim should depend from claim 7.

4. Claim 10 recites the limitations "**the treatment device**" and "**the optional step (b)**" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the broader claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names **joint inventors**. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schapira et al (US 5,349,874; IDS) in view of Ceri et al (US 2001/0049975 A1; IDS).

Claims are generally directed to "a method for detecting the presence of biofilm-forming microorganisms in a paper or board making process for determining the need of an anti-biofilm agent in the process, characterized by the steps **comprising**:

(a) subjecting a sampler device in the process line for a period of time to enable said microorganisms to form a biofilm *in situ* in said process on the surface of the sampler, (b) treating the surface of the sampler with said formed biofilm thereon in a solution of a test anti-biofilm agent for a period of time, then (c) contacting the surface of the sampler with said biofilm thereon with a liquid growth medium in a recession of a culturing device for a period of time, (d) removing the growth solution and the surface of the sampler from the recession of said device and detecting qualitatively and/or quantitatively the presence or absence of biofilm-forming microorganisms adhered on the walls of the recession" (see also recitation of claims 2-10).

Schapira et al (IDS) disclose a method for microbiological monitoring (see abstract, summary of the invention on columns 1, 3-4, and claims), wherein the method comprises the method steps of subjecting a sampler device (i.e. the stud; see figures 1-4, columns 4-5) in the process line for a period of time to enable said microorganisms to form a biofilm *in situ* in said process on the surface of the sampler (see column 4, lines 4-19), treating the surface of the sampler with said formed biofilm thereon in a solution of a test anti-biofilm agent for a period of time (such as an acid solution; see columns 6, 8 and 10), then contacting the biofilm with a growth medium in a recession of a culturing

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device for a period of time (i.e. using agar plates as culturing device; see columns 9-10), and quantitatively detecting the presence or absence of biofilm-forming microorganisms adhered on the walls of the recession (see column 10, table 1, in particular).

However, Schapira et al do not explicitly disclose the process steps as recited in claims 2, and 4-6 using a device that has a **“plurality of elongated protrusions”** connected to a support, and that can be used with a treatment and culturing device (having a recession and liquid growth medium) for **screening anti-biofilm agents** wherein the biofilms are formed on the surface of each protrusion (see instant claims 7-10, in particular), and with an arrangement that provides for **“one protrusion in each recession”** (of treatment or culturing devices) such as using multi-well plates each having pins or pegs in a row fixed on a corresponding support plate.

Ceri et al (IDS) disclose a process and a device (see abstract, summary of the invention, and claims) having protrusions (in a row that can be arranged and used with a multi-well device for treatment, and/or culturing steps using liquid growth media and/or treatment solutions; see figures 1-13, pages 2-3, in particular) for testing effects of anti-microbial agents on the formation of biofilms on the surface of said protrusions, wherein the geometry of the device (in terms of number, shape and size of the protrusions and their specific arrangements), time, temperature and other relevant parameters for treatment and culturing can be varied depending on the of the particular requirements (see pages 3-4, and examples on page 6, in particular).

Therefore, given the detailed description for the method of testing antimicrobial agents for the formation of biofilms using a device having protrusions as disclosed by

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the invention of Ceri et al, it would have been obvious to a person of ordinary skill in the art, at the time this invention was made to modify the method of Schapira et al such that it uses the device of Ceri et al for performing the process of detecting the presence of biofilm-forming microorganisms in a paper or board making process for the determining the need of an anti-biofilm agent in the process. Since, Ceri et al disclose all the method steps and a sampler device having elongated protrusions (akin to pins or pegs as claimed; see instant claims 7-10) that can be further modified and used in order to screen various anti-microbial agents, a person of ordinary skill in the art would have been motivated to modify the method of Schapira et al with the method disclosed by Ceri et al for detecting the biofilm forming microorganisms (and for selecting most efficient anti-biofilm agent) with a reasonable expectation of success. Since, Ceri et al disclose various arrangements of the protrusions (i.e. size, shape and number, etc.), various durations for incubations, temperatures and steps of treatment and culturing, which can be further modified as per need (such as parameters of instant claim 3), in the absence of any evidence to contrary, such process steps as claimed would have been obvious to an artisan of ordinary skill in the art at the time the claimed invention was made. The method steps that have been recited as "optional" (see instant claims 6, 9 and 10, in particular) have not been given much patentable weight, as they are not required by the inventions as claimed. The invention as claimed does not distinguish itself over the combined teachings of the cited prior art references.

Thus, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the art at the time the claimed invention was made.

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As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Conclusion

NO claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SATYENDRA K. SINGH whose telephone number is (571)272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Satyendra K. Singh/
Examiner, Art Unit 1657

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657